Confirmation No. 6892
Atty. Docket No. GP107-03.DV1

AMENDMENT

IN THE CLAIMS

Claims 1-12 stand withdrawn, and claims 1 and 8-20 have been amended as shown.

1. (Withdrawn - Currently amended) A method of detecting *Mycobacterium* species present in a biological sample, comprising the steps of:

providing a biological sample containing nucleic acid from at least one *Mycobacterium* species comprising a *Mycobacterium* 16S ribosomal RNA (rRNA) or DNA encoding a *Mycobacterium* 16S rRNA;

amplifying the Mycobacterium 16S rRNA or Mycobacterium DNA encoding the Mycobacterium 16S rRNA in an in vitro nucleic acid amplification mixture comprising at least one polymerase activity, and a combination of at least two primers having sequences selected from the group consisting of a first primer of SEQ ID NO:11 and a second primer that is an oligonucleotide consisting of 19 to 25 bases that contains contiguous bases 1 to 18 of SEQ ID NO:24 and optionally three to seven bases 5' to the contiguous bases 1 to 18 of SEQ ID NO:24 and/or optionally one base 3' to the contiguous bases 1 to 18 of SEQ ID NO:1 to SEQ ID NO:34, SEQ ID NO:37 and SEQ ID NO:38 to produce amplified Mycobacterium nucleic acid; and

detecting the amplified Mycobacterium nucleic acid by detecting a label associated with the amplified Mycobacterium nucleic acid.

2. (Withdrawn - Original) The method of Claim 1, further comprising in the steps of: adding to the biological sample at least one capture oligonucleotide that specifically hybridizes to the Mycobacterium 16S rRNA and an immobilized nucleic acid that hybridizes to the capture oligonucleotide under hybridizing conditions to produce a hybridization complex;

Filed: September 18, 2003

Confirmation No. 6892 Atty, Docket No. GP107-03.DV1

AMENDMENT

and

separating the hybridization complex from other components of the biological sample before the amplifying step.

- 3. (Withdrawn Original) The method of Claim 1, wherein the amplifying step amplifies 16S rRNA or DNA encoding 16S rRNA from M. tuberculosis or a Mycobacterium other than tuberculosis (MOTT) species.
- 4. (Withdrawn Original) The method of Claim 1, wherein the amplifying step amplifies 16S rRNA or DNA encoding 16S rRNA from M. abscessus, M. africanum, M. asiattcum, M. avium, M. bovis, M. celatum, M. chelonae, M. flavescens, M. fortuitum, M. gastri, M. gordonae, M. haemophilum, M. intracellulare, M. interjectum, M. intermedium, M. kansasti, M. malmoense, M. marinum, M. non-chromogenicum, M. paratuberculosis, M. phlei, M. scrofulaceum, M. shimodei, M. simiae, M. smegmatis, M. szulgai, M. terrae, M. triviale, M. tuberculosis, M. ulcerans or M. xenopi.
- 5. (Withdrawn Original) The method of Claim 1, wherein the detecting step uses at least one probe that hybridizes specifically to the amplified *Mycobacterium* nucleic acid.
- 6. (Withdrawn Original) The method of Claim 5, wherein the detecting step uses at least one labeled probe that hybridizes specifically to the amplified Mycobacterium nucleic acid.
- 7. (Withdrawn Original) The method of Claim 5, wherein the detecting step uses a plurality of probes that hybridize specifically to the amplified Mycobacterium nucleic acid.

Filed: September 18, 2003

Confirmation No. 6892 Atty, Docket No. GP107-03.DV1

AMENDMENT

8. (Withdrawn - Currently amended) The method of Claim 1, wherein the amplifying step uses a combination of at least a first primer and a second primer, wherein the first primer is consists of SEQ ID NO:11 selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:12, and the second primer is selected from the group consisting of SEQ ID NO:21, SEQ NO:22, SEQ ID NO:23 and SEQ ID NO:13 to SEQ ID NO:34, SEQ ID NO:37 and SEQ ID NO:38.

9. (Withdrawn - Currently amended) The method of Claim 8, wherein the amplifying step uses a combination of at least a first primer and a second primer, wherein the first primer is selected from the group consisting of SEQ ID NO:7 to SEQ ID NO:12, and the second primer is consists of SEQ ID NO:21, selected from the group consisting of SEQ ID NO:13 to SEQ ID NO:34, SEQ ID NO:37 and SEQ ID NO:38:

10. (Withdrawn - Currently amended) The method of Claim 8, wherein the amplifying step uses a combination of at least a first primer and a second primer consists of SEQ ID NO:22, selected from the group consisting of:

the first primer having the sequence of SEQ ID NO:7, and the second primer having the sequence of SEQ ID NO:13;

the first primer having the sequence of SEQ ID NO:7, and the second primer having the sequence of SEQ ID NO:14;

the first primer having the sequence of SEQ ID NO:7, and the second primer having the sequence of SEO ID NO:15;

the first primer having the sequence of SEQ ID NO:7, and the second primer having the sequence of SEO ID NO:16:

- the first primer having the sequence of SEQ ID NO:8, and the second primer having the

Filed: September 18, 2003

Confirmation No. 6892 Atty. Docket No. GP107-03.DV1

AMENDMENT

| sequence of SEQ ID NO:13; | |
|--|---------------|
| the first primer having the sequence of SEQ ID NO:8, and the second primer having the | - |
| sequence of SEQ ID NO:14; | |
| the first primer having the sequence of SEQ ID NO:8, and the second primer having the | - |
| sequence of SEQ ID NO:15; | |
| the first primer having the sequence of SEQ ID NO:9, and the second primer having the | - |
| sequence of SEQ ID NO:13; | |
| the first primer having the sequence of SEQ ID NO:9, and the second primer having the | - |
| sequence of SEQ ID NO:14; | |
| the first primer having the sequence of SEQ ID NO:9, and the second primer having the | 5- |
| sequence of SEQ ID NO:15; | |
| the first primer having the sequence of SEQ ID NO:10, and the second primer having the | he- |
| sequence of SEQ ID NO:16; | |
| the first primer having the sequence of SEQ ID NO:11, and the second primer having the | ie |
| sequence of SEQ ID NO:13; | |
| the first primer having the sequence of SEQ ID NO:11, and the second primer having the | ne- |
| sequence of SEQ ID NO:16;- | |
| the first primer having the sequence of SEQ 1D NO:11, and the second primer having the | ie |
| sequence of SEQ ID NO:17; | |
| the first primer having the sequence of SEQ ID NO:11, and the second primer having the | ic- |
| sequence of SEQ ID NO:18; | |
| the first primer having the sequence of SEQ ID NO:11, and the second primer having the | he- |
| sequence of SEQ ID NO:19; | |
| - the first primer having the sequence of SEQ ID NO:11, and the second primer having the | ic- |

Filed: September 18, 2003

Confirmation No. 6892 Atty. Docket No. GP107-03.DV1 AMENDMENT

sequence of SEQ ID NO:20; and

the first primer having the sequence of SEQ ID NO:12, and the second primer having the sequence of SEO ID NO:15.

- 11. (Withdrawn Currently amended) The method of Claim 8, wherein the amplifying step uses a combination of the first primer having the sequence of SEQ ID NO:11, and the second primer consists of SEO ID NO:23. having the sequence of SEO ID NO:16. SEO ID NO:39 or SEO ID NO:37.
- 12. (Withdrawn Currently amended) The method of Claim 8, wherein the amplifying step uses a combination of the first primer second primer consists of SEO ID NO:24, having the sequence of SEQ ID NO:11, and two second primers having the sequences SEO ID NO:16 and SEO ID NO:37.
- 13. (Currently amended) A composition for amplifying in an in vitro amplification reaction a *Mycobacterium* 16S rRNA sequence or a DNA encoding 16S rRNA, comprising a combination of at least two oligonucleotides, wherein a first oligonucleotide contains a promoter sequence and a sequence that hybridizes to a *Mycobacterium* 16S rRNA or DNA sequence, and a second oligonucleotide is an oligonucleotide consisting of 19 to 25 bases that contains, containing 18 contiguous bases 1 to 18 of SEQ ID NO:24 and optionally three to seven bases 5' to the 18 contiguous bases 1 to 18 of SEQ ID NO:24 and/or optionally one base 3' to the contiguous bases 1 to 18 of SEQ ID NO:24.
- 14. (Currently amended) The composition of Claim 13, wherein the composition comprises:

 at least one first oligonucleotide having the sequence consisting of SEQ ID NO:11 any one of SEQ ID NO:1 to SEQ ID NO:12, and

at least one second oligonucleotide having the sequence of any one of consisting of SEQ ID

Application Serial No. 10/665,708 Filed: September 18, 2003 Confirmation No. 6892 Atty. Docket No. GP107-03.DV1 AMENDMENT

NO:21, SEQ ID NO:22, SEQ ID NO:23 or SEQ ID NO:24. SEQ ID NO:13 to SEQ ID NO:34, SEO ID NO:37 or SEO ID NO:38:

15. (Currently amended) The composition of Claim 14, wherein the composition comprises:

the at least one first oligonucleotide containing the sequence of any one consisting of SEQ ID NO:11 7-to SEQ-ID NO:12, and

the at least one second oligonucleotide consisting of SEQ ID NO:21, containing the sequence of any one of SEO ID NO:13 to SEQ ID NO:34, SEQ ID NO:37 or SEQ ID NO:38.

- 16. (Currently amended) A kit containing one or more oligonucleotides having a sequence selected from the group consisting of <u>SEO ID NO:21, SEO ID NO:22, SEO ID NO:23, and SEO ID NO:24, SEO ID NO:34, SEO ID NO:34, SEO ID NO:37 and SEO ID NO:38.</u>
- 17. (Currently amended) The kit of claim 16, <u>further</u> containing <u>an oligonucleotide consisting of SEQ</u> ID NO:11.
- at least one first oligonucleotide having the sequence of any one of SEQ ID NO:1 to SEQ ID NO:12: and
- at least one second oligonucleotide having the sequence of any one of SEQ ID NO:13 to SEO ID NO:34, SEO ID NO:37 or SEO ID NO:38:
- 18. (Currently amended) The kit of claim 17, containing

at least one a first oligonucleotide consisting of SEQ ID NO:11 containing the sequence of any one of SEQ ID NO:7 to SEQ ID NO:12, and

at least one second oligonucleotide containing the sequence of any one of consisting of SEQ ID

Application Serial No. 10/665,708 Filed: September 18, 2003

Confirmation No. 6892 Atty. Docket No. GP107-03.DV1 AMENDMENT

NO:21, SEQ ID NO:22, or SEQ ID NO:23, SEQ ID NO:13 to SEQ ID NO:34, SEQ ID NO:37 or SEQ ID NO:38:

- 19. (Currently amended) The composition of Claim 14, wherein the composition comprises: the at least one first oligonucleotide <u>consisting</u> of SEQ ID NO:11, and the at least one second oligonucleotide <u>consisting</u> of SEQ ID NO:23.
- 20. (Currently amended) The composition of Claim 14, wherein the composition comprises: the at least one first oligonucleotide consisting of SEQ ID NO:11, and the at least one second oligonucleotide consisting of SEQ ID NO:24.